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# Use of PEAK PlasmaBlade in implant -based breast reconstruction and radiotherapy: new strategy to reduce complications

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## Abstract

**Background:** Implant-based breast reconstruction in the setting of radiotherapy often leads to higher complications rates (mainly capsular contracture and wound dehiscence) and poor cosmetic outcomes. We hypothesized that the combination of pulsed-electron avalanche knife (PEAK) PlasmaBlade (a pulsed radiofrequency electrosurgery) and acellular dermal matrix Veritas® in postmastectomy radiotherapy implant-based breast reconstruction could result in lower complications rate, better reconstructive results, and patient satisfaction.

**Methods:** A prospective observational study focused on the use of PEAK PlasmaBlade in implant-based breast reconstruction and radiotherapy was carried out in the Plastic Reconstructive Surgery Unit at Fondazione IRCCS Istituto Nazionale Tumori Milano between December 2017 and 2019 (2017–2018: enrollment; 2018–2019: follow-up). Patient demographics were queried and complication rates and patient and surgeon satisfaction were assessed.

**Results:** A total of 88 patients were enrolled; 2 patients received bilateral reconstruction, leading to a total of 90 procedures. Sixty-two women received contralateral symmetrization. Seroma was the most frequent minor complication (8.8%); implant exposure was the most recorded among major complications (5.5%). Preoperative lipofilling was the most substantial protective factor for preventing complications ($p < 0.001$). A significant association between capsular thermal damage thickness and the type of electrosurgery used (traditional electrosurgery vs PEAK PlasmaBlade) was observed, with lower values with PEAK PlasmaBlade ($p < 0.0001$).

**Conclusions:** Our protocol results in low rates of surgical complications and a high level of patient and surgeon satisfaction although longer follow-up is needed.

## Keywords

Implant-based breast reconstruction, capsular contracture, PEAK PlasmaBlade, acellular dermal matrix, breast reconstruction and radiotherapy, complications in breast reconstruction

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## Introduction

Breast cancer is the commonest non-skin malignancy in the female population and the second most common cancer overall.[1] An increasing number of women undergoing mastectomy tend to choose one-stage or two-stage immediate implant-based breast reconstruction (BR) as part of the treatment because BR supports patient recovery and reduces psychological morbidity associated with the loss of the breast.[2]

Since recent studies have demonstrated that postmastectomy radiotherapy (PMRT) can reduce locoregional

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recurrence and improve disease-free status, as well as overall survival,[3] the number of patients receiving PMRT is growing,[4] even though integrating BR and radiotherapy continues to be an area of concern, as it affects reconstructive and cosmetic outcomes. PMRT is associated with a higher risk of acute and chronic complications rate, such as subcutaneous fibrosis, capsular contracture, breast distortion, chest wall pain, tightening and thinning of tissues, implant exposure, and unsatisfactory cosmetic outcomes.[5–7] The chronic ischemic status of the irradiated tissue has constituted fat grafting applicability rationale for tissue quality improvement and decreasing chest wall pain, even though it is not a suitable option for capsular contracture treatment. Fat grafting is generally performed in the layer between skin and capsule, encompassing the entire soft tissue envelope overlying the implant, resulting in increasing amount, pliability, and vitality of tissues.[8]

Capsular contracture represents the most frequent complication experienced in PMRT implant-based BR[5,7] and although not life-threatening, it causes significant discomfort and psychological distress and adversely affects quality of life. Capsular contracture preventative measures such as sterile, atraumatic techniques, meticulous hemostasis, local antimicrobial agents, and textured implants are well described.[9–11] Despite the fact that corrective surgery is the only treatment, the recurrence rate is still high,[12] and whereas data on capsulectomy are less conclusive, a consistently low capsular contracture recurrence rate is observed with acellular dermal matrix (ADM).[13] The ADM, placed in the site of capsulectomy, acts as an antigen-free barrier between the new implant and host tissue, diminishing host immune response and capsule reformation,[12,14,15] and constitutes a reinforcement layer in thin breast tissue areas.

Pulsed-electron avalanche knife (PEAK) PlasmaBlade (PeakPB; Medtronic Advanced Energy) is an innovative electrosurgical device that works with radiofrequency brief high-frequency pulses, using less total energy and operating at significantly lower temperatures than traditional electrosurgery (40°C–170°C vs 200°C–350°C).[16] PeakPB incisions have demonstrated reduced thermal injury depth, inflammatory response, and scar width in healing skin compared with traditional electrosurgery, suggesting clinical meaningful advantages during wound healing.[16–19]

We hypothesized that the PeakPB combined with the use of ADM Veritas (Synovis Surgical Innovations) would have superior wound-healing profile, fewer capsular contractures, and lower complications rate compared with traditional approach in expander or implant replacement in women undergoing mastectomy and radiotherapy.

## Methods

### *Patients and study design*

A prospective observational study focused on the use of PeakPB in implant-based BR and radiotherapy was started in the Plastic Reconstructive Surgery Unit at Fondazione IRCCS Istituto Nazionale Tumori Milano in December 2017. The pericardium bovine ADM Veritas was used in all patients to complete the reconstruction. The protocol for this clinical study was approved by the Institutional Review Board (INT 138/17) and conducted in accordance with all accepted standards for human clinical research. All patients gave written informed consent before study enrollment.

Inclusion criteria were mastectomy, radiotherapy, and reconstruction with expander or implant and capsular contracture grade 3 or 4 according to Baker scale. Exclusion criteria were the need for autologous reconstruction, autoimmune disease, use of corticosteroids, and chemotherapy-immunosuppressive therapies.

Between December 2017 and December 2018, 88 patients were enrolled; two patients received bilateral reconstruction for a total of 90 procedures. Patients underwent 1 year follow-up.

The entire patient cohort consists of the expander and implant group. The expander group was constituted of women who underwent expander reconstruction after mastectomy and subsequent radiotherapy; the implant group was represented by implant-based BR patients who had capsular contracture due to previous radiotherapy (Spear-Baker grade III or IV)[20] and were candidate to implant replacement.

Among the overall population, some patients received preoperative lipofilling (from one to four treatments), depending on the cutaneous and subcutaneous tissues quality, to prevent capsular contracture onset and recurrence in the expander and implant group, respectively, as well as to lower the overall complications rate.

A dedicated database was prospectively collected with preoperative and postoperative clinical data including sociodemographic characteristics (i.e. age, body mass index, smoking, and comorbidities), surgical details (i.e. date/type of mastectomy and reconstruction), tumor histology, treatment data (i.e. chemotherapy, hormonal therapy), details of radiotherapy (timing, Gray), and capsular contracture grade. Clinical outcomes such as postoperative complications, unplanned secondary operations, revision procedures, and surgeon and patient satisfaction were also recorded. Postoperative complications were classified as major (i.e. major skin flap necrosis, major cellulitis requiring intravenous antibiotics, implant exposure with subsequent implant loss, hematoma, capsular contracture [Spear-Baker Grade III or IV[20]], and recurrent seroma) and minor (i.e. minor skin flaps necrosis and cellulitis requiring only oral antibiotics and seroma not requiring reoperation). Major complications were also classified as surgery-related or not surgery-related.

### *Surgical technique and perioperative care*

Preoperative and postoperative evaluations, as well as data collection, were performed by the same surgeon (L.S.). All patients received perioperative care and surgical treatment

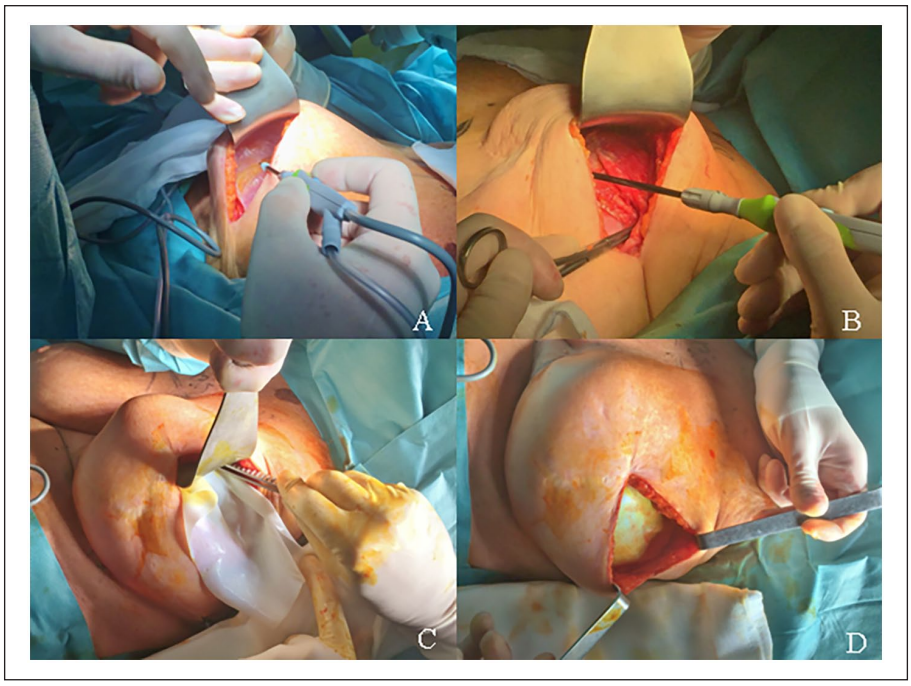


**Figure 1.** Intraoperative view of inframammary fold definition by means of fascia superficialis incision (A) and capsulectomy (B) with pulsed-electron avalanche knife (PEAK) PlasmaBlade in a patient undergoing implant replacement. After submuscular positioning of the anatomic textured implant, the lower pole is covered with ADM (C–D), which constitutes an additional layer over the implant, reducing the risk of implant exposure.

from the senior author (U.C.) and two members of his team (L.S.; S.B.). All surgeries were performed under general anesthesia by standard techniques. Prophylactic antibiotics were delivered intravenously upon anesthesia initiation. Expander or implant replacement with prosthesis was performed with PeakPB. All patients underwent capsulectomy, during which two capsular specimens were taken. Natrelle 410 (Allergan, Inc.) textured anatomic implants were placed submuscularly and were covered with the ADM Veritas, especially at the lower pole (Figure 1). Before implant placement, the pocket was irrigated with rifampicin. Pectoralis major muscle was sutured above the ADM. One suction drain was placed. All patients were administered oral antibiotics until drain removal. Suction drainage was applied until $<30$ mL were collected in 24 hours.

## *Capsular histologic analysis*

A total of two specimens of the periprosthetic capsule were collected from each patient: one taken with PeakPB and one with traditional electrosurgery. Each specimen was placed in 10% formalin for permanent sectioning, paraffin embedded, and tangentially sectioned to create 10-µm sections, stained with hematoxylin & eosin and Masson trichrome stain. All specimens were evaluated by light microscopy by a single pathologist (A.F.) in a blinded manner. Acute thermal injury was determined as a maximum width of the zone of coagulation necrosis.

## *Patient and surgeon satisfaction*

The surgeon assessed BR quality in terms of shape, symmetry with the contralateral breast, and comprehensive outcome, considering tissue characteristics and radiodamage. To simplify patient satisfaction assessment, a single question was asked: "Are you satisfied with the overall quality of the reconstruction?" The possible answers were highly satisfied, quite satisfied, or unsatisfied.

## *Statistical analysis*

Patient characteristics were summarized using basic descriptive statistics according to variables' underlined nature. Association between complications onset and sociodemographic characteristics as well as preoperative lipofilling and tissues quality were assessed by Kruskal-Wallis test and Fisher exact tests, respectively, for the continuous and categorical variables. To assess the pattern of concordance between patient and surgeon satisfaction (at 12 months after surgery), the raw data distribution was dichotomized as "highly satisfied" or "quite satisfied or unsatisfied." The Cohen kappa statistic and its 95% confidence interval[21] were estimated and interpreted in a qualitative manner on the basis of the Landis and Koch classification criteria.[22] Prevalence-adjusted and bias-adjusted kappa (PABAK) was also computed to account for imbalance of prevalence.[23] To evaluate the relationship between capsular thermal damage

**Table 1.** Characteristics of the study cohort.

| Clinicodemographic data (n = 88) | N | % |
|---|---|---|
| Age, y, median (range) | 55 (34–75) | |
| BMI, kg/m$^2$, median (range) | 24.04 (17.8–40.4) | |
| Smoking status | | |
| Current smokers | 17 | 19.32 |
| Former smokers | 16 | 18.180 |
| Nonsmokers | 55 | 62.50 |
| Comorbidities | | |
| Surgery related[a] | 15 | 17.05 |
| Not surgery related | 7 | 7.95 |
| No | 66 | 75.00 |
| Concomitant contralateral symmetrization | | |
| Yes | 62 | 70.45 |
| No | 24 | 27.27 |
| Bilateral | 2 | 2.27 |
| Postoperative additional procedures (within 12 months FU)[b] | | |
| Yes | 5 | 6.02 |
| No | 78 | 93.98 |
| Mastectomy | | |
| Nipple-sparing | 19 | 21.11 |
| Skin-reducing | 2 | 2.22 |
| Skin-sparing | 3 | 3.33 |
| Total | 66 | 73.33 |
| Axillary procedure | | |
| Lymph node biopsy | 11 | 12.22 |
| Axillary dissection | 77 | 85.56 |
| None | 2 | 2.22 |
| Type of reconstruction | | |
| Expander | 41 | 45.56 |
| Implant | 49 | 54.44 |
| Implant size, mL, median (range) | 525 (180–775) | |
| Suction drainage appliance, d, median (range) | 20 (7–53) | |

BMI: body mass index; FU: follow-up.
[a]Hypertension or diabetes.
[b]Four patients died during 12-month FU and one patient was lost to FU.

thickness distribution and the use of traditional or PeakPB, the nonparametric Wilcoxon signed-rank test for paired data was used. All statistical analyses were carried out with SAS software (version 9.4; SAS Institute) by adopting an alpha level of 0.05.

## Results

The considered cohort consisted of 88 patients for a total of 90 surgical procedures, as two patients underwent bilateral BR. Four patients died during the study period so did not complete 1-year follow-up. Table 1 reports the main clinical and demographic characteristics at surgery as well as the surgical characteristics of the considered cohort.

### *Onset of complications*

Nine patients experienced minor complications: eight patients had seroma and one patient wound dehiscence. Considering major complications related to surgery, five patients developed skin flaps necrosis and subsequent implant loss. Of those, one patient decided not to undergo any further surgery, whereas the remaining patients underwent autologous reconstruction: three latissimus dorsi flap with implant and one transverse rectus abdominal myocutaneous (TRAM) flap. Two patients had major cellulitis, implant removal, and subsequent reconstruction with TRAM flap. One patient experienced recurrent seroma, which benefited from capsulectomy and implant exchange.

With respect to complications not related to PeakPB, one patient had a traumatic hematoma requiring reoperation 2 weeks after surgery, and two patients, who had preexisting thin tissues, reported a sunburn consisting of implant exposure and need for autologous reconstruction with latissimus dorsi flap with implant and TRAM flap, respectively.

As regards the association between major complications onset and sociodemographic characteristics (smoking, age, and body mass index), no significant associations were found

(Table 2). A statistically significant association between major complications onset and lipofilling was observed on the entire cohort ($p_{Fisher} < 0.001$) and in the implant group ($p_{Fisher} = 0.001$; Figure 2 [A]). Among patients who performed lipofilling before BR, 97.37% did not develop complications, whereas complication rate was superimposable in the group of patients without preoperative lipofilling. This association was retained by also considering the number of lipofilling procedures in the entire cohort ($p_{KW} = 0.007$) and within the implant group ($p_{KW} = 0.004$; Figure 2 [B]): no major complication was observed in those who underwent two or more lipofilling procedures. With respect to tissue quality, a significant association was observed in both expander ($p_{Fisher} = 0.035$) and implant groups ($p_{Fisher} = 0.042$) as well as on the entire series ($p_{Fisher} = 0.003$). No statistically significant association was observed in the expander group for lipofilling procedure ($p_{Fisher} = 0.142$; Figure 2 [C]) or number of lipofillings ($p_{KW} = 0.273$; Figure 2 [D]).

**Table 2.** Results from the association analysis between the complications onset and the sociodemographic characteristics.

| | Entire cohort | Expander group | Implant group |
|---|---|---|---|
| Smoking habits | 0.687 | 0.632 | 0.441 |
| Age[a] | 0.098 | 0.236 | 0.195 |
| BMI[a] | 0.956 | 0.457 | 0.585 |

BMI: body mass index.
[a]Kruskal-Wallis *p* value.

## *Capsular contracture*

No capsular contracture was recorded in patients who replaced the expander with implant.

In the implant group, all but two patients dropped to grade I or II at 12 months follow-up. The patient with sudden onset of Baker IV capsular contracture underwent latissimus dorsi flap reconstruction with implant because of lack of tissue, whereas the patient with Baker III capsular contracture decided not to undergo any further surgery.

## *Histologic evaluation of thermal damage-related capsular artifacts and thickness*

Significant association between artifacts thickness and electrosurgery (traditional electrosurgery vs PeakPB) was observed in the entire cohort ($p_{WSR} < 0.001$) as well as in

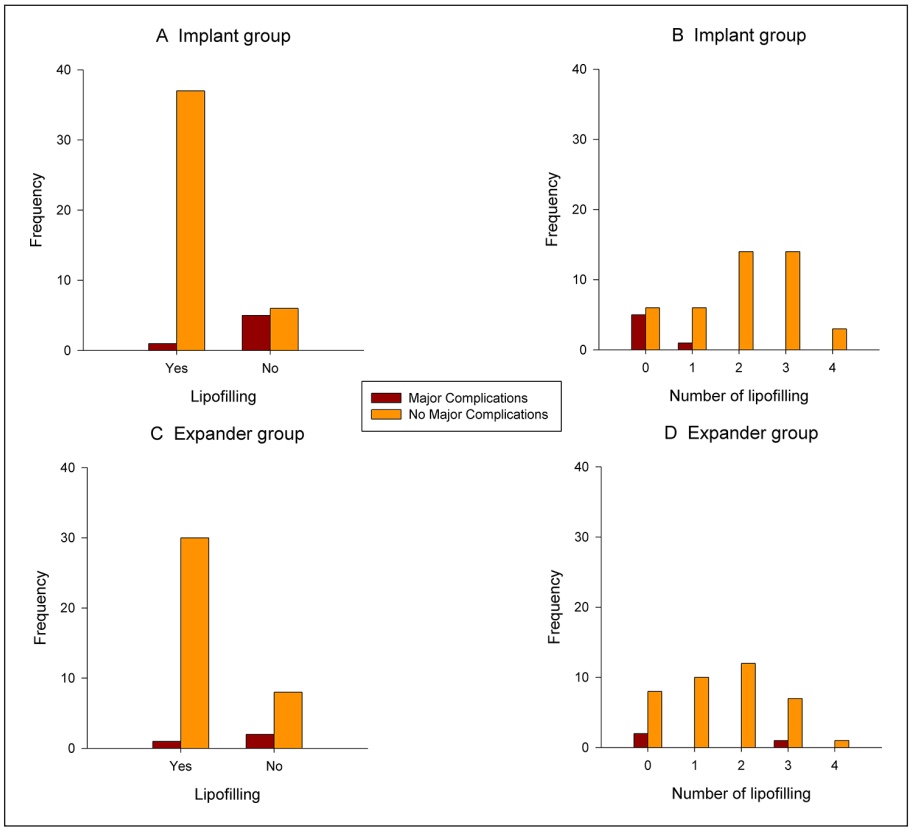


**Figure 2.** Bar charts depicting the frequency distribution of the onset of major complications after implant replacement according to the preoperative lipofilling procedure (A) and the number of lipofilling procedures (B). (C) Frequency distribution of the onset of major complications according to the preoperative lipofilling procedure and the number of lipofilling procedures (D) among women who underwent expander reconstruction after mastectomy are shown.

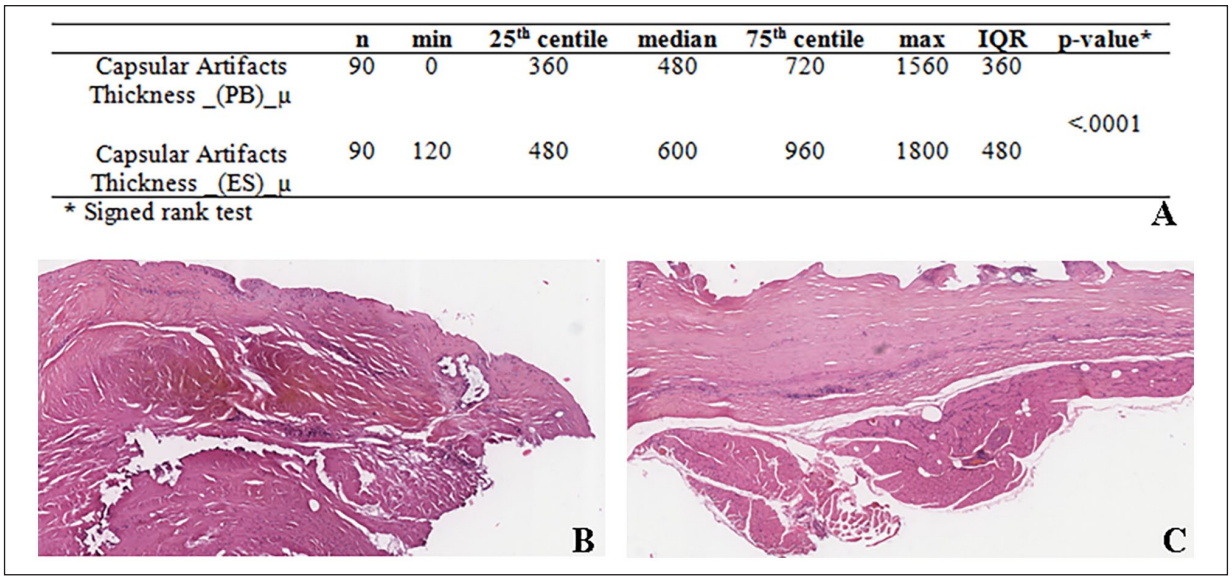


**Figure 3.** (A) Descriptive statistics of artifact thickness, according to the type of electrosurgery, on the entire cohort. (B, C) Representative histologic images of thermal damage with traditional electrosurgery and pulsed-electron avalanche knife (PEAK) PlasmaBlade, respectively. (B) Greater thermal damage compared to (C).

**Table 3.** Evaluation of preoperative and postoperative pain.

| Preoperative pain | Postoperative pain at 12 months | | | | |
|---|---|---|---|---|---|
| | None | Slight | Moderate | Strong | Total |
| None | 32 | 1 | 0 | 0 | 33 |
| Slight | 36 | 2 | 0 | 0 | 38 |
| Moderate | 8 | 1 | 0 | 0 | 9 |
| Strong | 3 | 2 | 0 | 0 | 5 |
| Total | 79 | 6 | 0 | 0 | 85 |

both the expander ($p_{WSR} < 0.001$) and implant group ($p_{WSR} = 0.032$), with higher values vs the traditional group (Figure 3).

### *Evaluation of preoperative and postoperative pain*

The percentage of patients who reported at least slight preoperative pain (Table 3) was drastically decreased at 12-month follow-up (from 62.22% to 6.67%): no patient showed moderate or severe pain and only few reported mild pain. Among the group of patients with moderate or severe presurgery pain, 83.3% of patients experienced no pain at 12 months follow-up, in both expander and implant groups.

### *Postoperative satisfaction*

Both patients and surgeons had good postoperative satisfaction (Figure 4–6). Specifically, 74.44% of patients reported good satisfaction, as did 80% of surgeons. Table 4 reports the concordance between the two. A substantial level of agreement, according to Landis and Koch classification criteria, was observed in the expander group ($\kappa = 0.771$; 95% CI, 0.466–1.00) and a moderate level in the implant group ($\kappa = 0.575$; 95% CI, 0.304–0.847) by considering the dichotomized satisfaction perception. Of note, by considering the PABAK values, a higher level of agreement was observed in both the groups: 0.696 (95% CI, 0.903–0.488) and 0.897 (95% CI, 0.759–1.000) for the implant and expander group, respectively.

## Discussion

Although the use of ADM in BR is widely debated, the use of PeakPB is currently described in several articles,[18,19,24–27] but not concerning implant-based BR. The present study is the first study that analyzes the use of PeakPB in implant-based BR and radiotherapy.

Before this protocol in irradiated patients undergoing expander or implant replacement, one single device (PeakPB or ADM) was routinely used, achieving encouraging outcomes. We decided to evaluate their combination.

Although we do not know if PeakPB and ADM have reduced our complications rate, our study illustrated their potential synergy on capsule formation, as if the better wound healing profile of PeakPB could enhance ADM features. More precisely, acting as an additional vascularized layer over the implant, the ADM allows for rapid host revascularization and cell repopulation, and inhibits pseudoepithelium development, constituting at the same time a

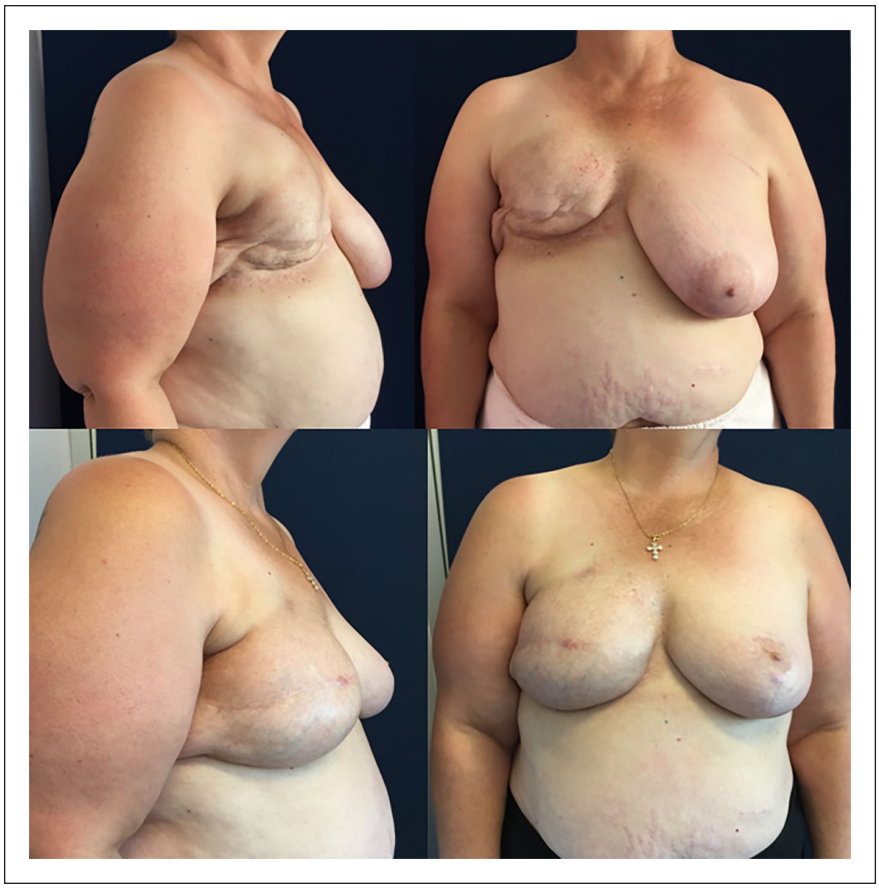

**Figure 4.** Preoperative and postoperative pictures of a 57-year-old patient who underwent modified mastectomy with expander and radiotherapy. She underwent expander replacement with implant and contralateral breast reduction. Pictures at 1 year follow-up (below) show good cosmetic outcomes.

barrier to the host immune response against a foreign body. These characteristics contribute to capsular contracture incidence reduction, as demonstrated histologically and clinically.[28,29] On the other hand, PeakPB ensures tighter scars, more superficial zones of thermal injury, and stronger healed incisions, as well as a lower degree of inflammation with better reepithelialization, as already demonstrated on porcine skin,[17] rat fascia,[30] and human model.[16]

The use of both ADM and PeakPB positively affected postoperative pain. The majority of patients with moderate to severe preoperative pain had no pain at 12-month follow-up. This outcome reflects Spear-Baker capsular contracture grade I or II and the beneficial effects of ADM on tissue healing processes. In addition, ADM provides support to the inferior pole of the implant, implementing postoperative discomfort reduction.

As regard to complications, the high complication rates in PMRT implant-based BR (58.8%)[31–36] and in PMRT implant-based BR with ADM (47.7%)[37] are well reported in the literature. Our overall surgery-related complications rate was 21.1% (10% minor and 11.1% major complications). The most minor complication observed was seroma (8.8%), with no difference between expander and implant group.

It is well known that ADM has a higher seroma rate prior to its incorporation, especially in irradiated tissues; however, the advantages of using ADM are important. The comparison of our data with other studies focused on the impact of ADM in PMRT and implant-based BR; compared with the review of Craig et al.[37] (13.6%) and the study by Israeli and Feingold[36] (13%), our incidence of seroma is slightly lower (8.8%). We hypothesize a crucial role played by PeakPB.

All previous studies on PeakPB showed a significant lesser incidence of seroma compared with traditional electrosurgery. This represents an interesting result considering the fact that seroma is one of the most frequent complications in mastectomy (10% with PeakPB vs 37.5% with electrosurgery),[26] abdominoplasty (0% vs 15.4%),[24] and latissimus dorsi flap (19% vs 47.8%).[27] The lower seroma incidence could result from lower PeakPB temperature with reduced thermal injury to tissue, small vessels, and lymphatics.

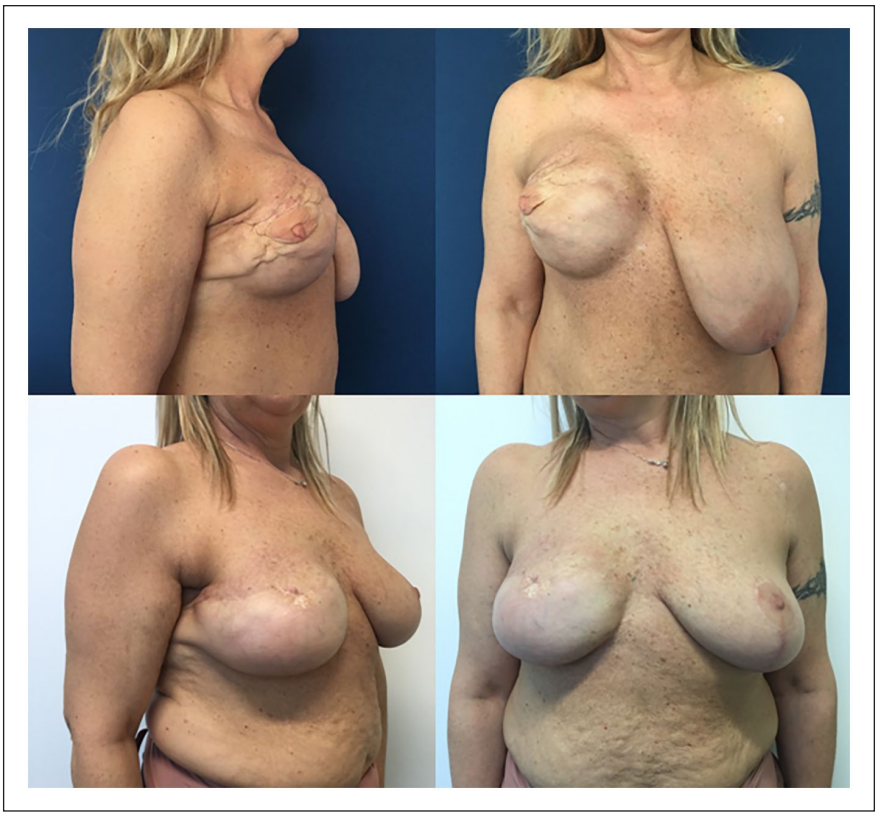

**Figure 5.** This 58-year-old woman underwent nipple-sparing mastectomy with Becker expander in another hospital and adjuvant radiotherapy. (Above) She underwent expander replacement with implant and contralateral reduction mammaplasty and nipple areola complex graft. The 12-month follow-up pictures show satisfactory results (below).

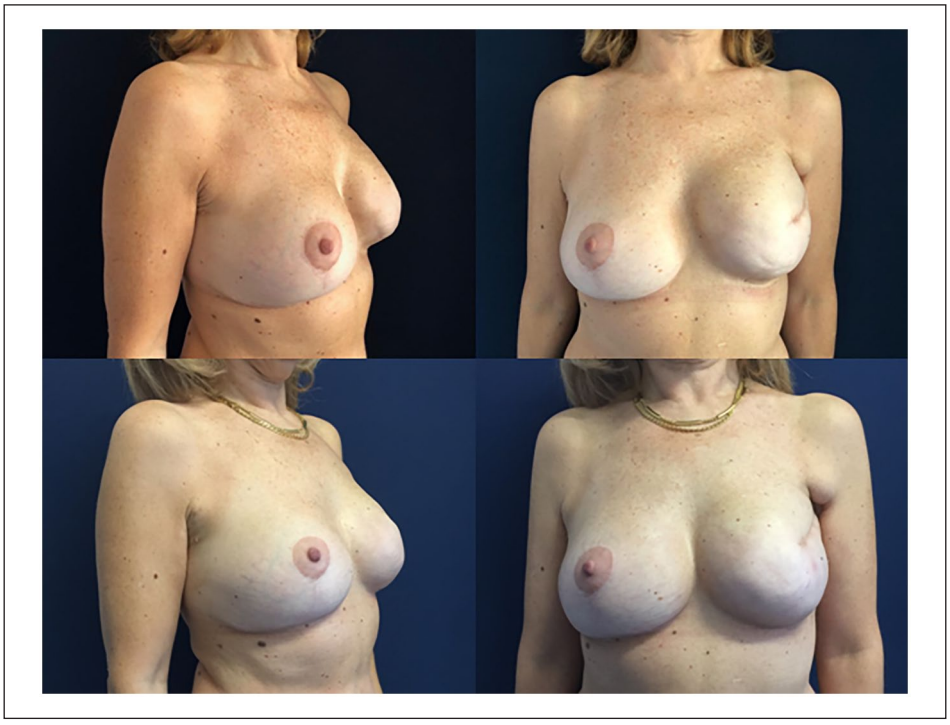

**Figure 6.** This 60-year-old patient underwent unilateral implant replacement for Spear-Baker IV capsular contracture (above) with a good cosmetic result at 12-month follow-up (below).

**Table 4.** Comparison of postoperative satisfaction between patients and surgeons.

| Patient satisfaction | Surgeon satisfaction | | | |
|---|---|---|---|---|
| | Unsatisfied | Quite satisfied | Highly satisfied | Total |
| Unsatisfied | 2 | 1 | 3 | 6 |
| Quite satisfied | 1 | 7 | 4 | 12 |
| Highly satisfied | 0 | 2 | 65 | 67 |
| Total | 3 | 10 | 72 | 85 |

The comparison of our histologic findings regarding capsular thermal damage (as a specimen of irradiated tissue) showed less thermal injury depth of PeakPB when compared to traditional electrosurgery (480 µm vs 600 µm), as already reported in previous clinical studies.[18,24,25,30]

With regard to major complications, the most common complication observed was implant exposure (5.5%), followed by major cellulitis (2.2%), capsular contracture (2.2%), and seroma (1.1%).

According to skin and tissues quality preoperative evaluation, we observed that major complications (implant exposure predominantly) seemed to be related to poor quality tissues. In this group of patients, the possibility of higher complications rate due to poor implant coverage was considered. The ideal reconstruction would have been a flap, but patients refused this demanding surgery and when informed about the risks of failure of implant-based BR, they agreed to try our surgical protocol.

The observed lack of major complications within the implant group in patients who underwent two or more lipofilling procedures was interesting. Local restoration of irradiated tissues would allow a safer implant placement even in patients with satisfying local characteristics. The beneficial effects of transferred fat on irradiated tissues have been demonstrated in various clinical contexts.[38–40] Adipose-derived stem cells improve skin and subcutaneous tissue quality, promoting new vessels growth and regeneration. In addition, fat graft increases tissue thickness, reducing the possibility of implant exposure in case of wound dehiscence, and improves cosmetic reconstructive outcomes. However, this surgical technique presents several limitations: it requires many surgical procedures and delays BR completion. This multiple step approach could be frustrating for patients. Nevertheless, our results underlined lipofilling's fundamental role in irradiated patients.

The scant incidence of capsular contracture after 1 year follow-up was encouraging, with only 2.2% of capsular contractures among the implant group and no onset in the expander group. Over the past decade, the introduction of ADM in BR has coincided with capsular contracture rate reduction, so the expectation is that ADM may protect against radiotherapy's detrimental effects. The majority of ADM studies have predominantly included nonirradiated cohorts, although some studies did include irradiated patients, who did not appear to have an increased risk of contracture.[41,42] Our capsular contracture rate seems to have a similar incidence to that of Spear et al.[41] and Salzberg at al.,[43] while Spear et al.[44] and Moyer et al.[45] reported a higher rate of capsular contracture (>30%).

Regarding study limitations, a longer follow-up period is needed to assess whether the combination of PeakPB and ADM could lead to long-term low rate of capsular contracture as well as that of a control set for group comparison.

One significant disadvantage concerning the use of ADM and PeakPB could be the considerable cost added to the initial procedure, given the economic constraints of the provision of BR procedures and health care. Nevertheless, our study corroborates that the use of ADM and PeakPB in PMRT implant-based BR was cost-effective because of its benefits in successful reconstructions and reduced complications rate with subsequent lower reoperations.

## Conclusion

A further option for BR in irradiated patients can be successfully added according to our surgical strategy that results in low rates of complications and a high level of patient and surgeon satisfaction.

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